DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2007

Galt Medical Corporation
c/o Mr. David G. Catlin
Executive Vice President
2220 Merritt Drive
Garland, TX 75041

Re: K071330
Galtstick™ Introducer System
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel dilator for percutaneous catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: October 11, 2007
Received: October 12, 2007

Dear Mr. Catlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bahner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K071330

Device Name: Vessel Dilator/Introducer Galtstick™

Indications For Use: The Galtstick™ Introduce system is indicated for percutaneous introduction and place of catheters and guidewires.

Prescription Use ___X___ AND/OR Over-the Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna B. Lachman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071330

510K. Summary

JUL 31 2007

GALT MEDICAL CORP.

Special Premarket Notification
Galtstick™ Introducer System

K071330

GENERAL INFORMATION:

A. **Product Name: Dilator**

Trade Name: Galtstick™ Introducer System

Classification Name: Dilator, For Percutaneous Catheterization

B. **Establishment Registration Number:** Galt Medical Corp. has been assigned 1649395 as an establishment registration number.

C. **Classification:** Dilator has been classified as Class II and assigned a code of DRE by the Cardiovascular Panel.

D. **Performance Standards:** None established under section 514.

E. **Legally Market Device (unmodified):** The legally marketed device is a Co-Axial Dilator kit used for the same indications. They were released under 510(k) #K000737. This Premarket Notification 510(k) was originally submitted under the name of Xentek Medical. Xentek was a development company owned by Galt Medical Corp. Since that time all assets of Xentek including 510(k)s have been transferred to Galt Medical Corp.

F. **Comparison of modified device to legally marketed device:** The modified device and the legally marketed device use the same materials as listed on the original 510(k). The introducer sets use the same insert molded dilators, and dilator tubes. Labeling, packaging, and sterilization are the same. The Galtstick™ device adds a stiffening cannula with an attached hub for ease of insertion into the body.